



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20430
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,428	07/19/2003	Chad S. Hale	UVMO.007US/REH	2653

7590 07/29/2003

ROBERT E. HANSON
FULBRIGHT & JAWORSKI L.L.P.
SUITE 2400
600 CONGRESS AVENUE, SUITE 2400
AUSTIN, TX 78701

EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
----------	--------------

1632

11

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,428

Applicant(s)

HALE ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election without traverse of the invention of group II, claims 26-50 in Paper No. 10 is acknowledged.
2. Claims 1-50 are pending in the instant application.
3. Claims 1-25 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.
4. Claims 26-50 are instantly under consideration.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 26-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 and its dependent claims are vague and indefinite because it is unclear as to what is meant by the term "genetic polymorphism genetically linked to".

Claim 27 recites the limitation "said genetic polymorphism" in line 1. There is insufficient antecedent basis for this limitation in the claim because the independent claim 26 recites the terms "genetic polymorphism" and "said polymorphism". It is unclear as to which one these terms is referred to in the instant claim. Applicants are advised to use one term consistently- said polymorphism or said genetic polymorphism, preferably, said genetic polymorphism, the term first time used in claim 26.

Claim 34 is vague and indefinite because it recites a range "between about 16 and about 20 copies". The metes and bounds of the range are not clear because it is unclear as to what is encompassed by about 16 and about 20 copies.

Claim 49 is vague and indefinite because it recites a range "between about 2 and about 10 times". The metes and bounds of the range are not clear because it is unclear as to what is encompassed by about 2 and about 10 times.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 26-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al (Domestic Animal Endocrinology 17:421-437, 1999) in view of Aggrey et al (The Journal of Heredity 90: 148-151, 1999, Schmutz et al (Mammalian Genome 6:710-713, 1995) and Heap et al (Journal of Animal Science 73:1529-1530, 1995).

At time of the invention, Liu et al taught liver specific expression of the growth hormone receptor 1A was responsible for the Laron dwarfism in miniature Bos indicus cattle. The art by Liu et al also taught the presence and activity of two promoters P1 and P2 in the animal, P1 in the adult liver and P2 in adult liver and non-hepatic tissues and that the expression of GHR expression by P1 was regulated

during development, hormonal and metabolic signals, whereas the P2 promoter was a constitutive promoter (see introduction on page 422 and the abstract on page 421-422). The art further reviewed that the growth rate and mature height of the miniature cattle was about 70% of the normal cattle. The art also taught primers, PCR and other methodology for genetic analysis and gene expression analysis (see the methods and results sections on pages 423-431). Finally, the art taught that inactivation of GHR P1 or stability of GHR1A mRNA was responsible for this condition. The art by Liu et al does not teach breeding of beef cattle comprising genetic polymorphism linked to P1 promoter of exon 1A growth hormone receptor gene with another beef cattle to increase probability of obtaining beef cattle head comprising predisposition to increased or decreased carcass or weaning weight.

Aggrey et al teaches markers within regulatory region of the growth hormone receptor gene and that such markers are associated with milk related traits in Holsteins. The art also teaches use of PCT based selection method in breeding and use of polymorphism in marker-assisted selection in cattle (see the abstract). The art also teaches that selecting superior animals is a main goal of animal breeders and screening favorable alleles for selection at the DNA level provides an ideal tool for marker-assisted selection and that GHR provides one such genetic model (see the introduction).

Schmutz et al also teaches the role of DNA marker assisted selection in animal breeding, such as in Charolais cattle for polled condition (see the abstract and introduction).

At the time of the invention, it would have been obvious to an artisan of ordinary skill to breed beef cattle comprising genetic polymorphism linked to P1 promoter of exon 1A growth hormone receptor gene with another beef cattle to increase probability of obtaining beef cattle head comprising predisposition to increased or decreased carcass or weaning weight with a reasonable expectation of success by following the routine methods of breeding and DNA marker selection. An artisan would have been motivated to carry out such breeding because the relationship of P1 promoter of exon 1A growth hormone receptor gene with growth of cattle was well known at the time of the art and it was a normal practice in the


art among breeders to select animals with better traits in terms of milk production, quality of meat etc. Regarding the limitations of conditions of PCR, types of polymorphism, number of thymine guanine dinucleotide repeats, gel electrophoresis and different species of beef cattle, it is noted that such methods and breeding techniques between different species was common and well known (for example, see C2, C3, C7, C9, C21 etc. in the IDS).

10. No claim is allowed.

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.


RAM R. SHUKLA, PH.D
PATENT EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632